

## REMARKS

Claims 14-15, 17-26 and 28-29 are pending in the present application. By this amendment, Claims 14, 20, 22 and 25 are amended; and Claims 16 and 27 are canceled. Applicants respectfully request reconsideration of the present claims in view of the foregoing amendments and the following remarks.

### **I. Formal Matters:**

#### Rejections under 35 U.S.C. § 112, first paragraph

Claims 20 and 22-24 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being described in the specification in sufficient detail other than the preferred embodiments set forth in the specification. This rejection is respectfully traversed. It is respectfully submitted that an Applicant is not required to provide each and every possible embodiment for carrying out the functions listed in the specification, and that one of ordinary skill would be able to determine mechanisms and especially controllers that are capable of carrying out the functions claimed.

Applicants have amended the claims as requested by the Examiner in regards to the mechanism used to expedite prosecution. However, as there are many different types of controllers, and as many controllers are well known in the art, Applicants respectfully submit that there would be no undue experimentation necessary to obtain a non-circuit board controller capable of carrying out the desired functions. As such, unless the Examiner is able to provide some evidence that undue experimentation would be necessary for one of ordinary skill in the art to use a non-circuit board controller in the present invention, Applicants respectfully request withdrawal of this rejection.

### **II. Prior Art Rejections:**

Claims 22-26 and 28-29 are rejected under 35 U.S.C. §102(a) as being anticipated by or, alternatively under 35 U.S.C. §103(a) as being unpatentable over, WO 94/21117 to Nicolau (hereafter "Nicolau"). This rejection is respectfully traversed.

Claim 20 is directed to, *inter alia*, an electroporation chamber for poration of biological particles, the electroporation chamber being removably mounted to a support member, the electroporation chamber comprising walls defining a fluid flow path; electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source

of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field and a mechanism for breaking the electrodes prior to the apparatus being removed from the support member whereby the apparatus cannot be re-used; wherein the mechanism includes means that are connected to the electrodes employed in the electroporation chamber when the chamber is mounted to a support member for destroying the electrodes prior to the chamber being removed from the support member, wherein the electrical energy is a variable flux. Claim 22 is directed to, *inter alia*, an electroporation chamber for poration of biological particles, comprising walls defining a fluid flow path; electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field; a pump for moving the biological particles along the fluid flow path; and a controller responsive to the rate at which the pump moves the biological particles along the fluid flow path and to the interval between pulses of electrical energy, wherein the electrical energy is a variable flux. Claim 25 is directed to, *inter alia*, an electroporation chamber for poration of biological particles, comprising walls defining a fluid flow path; electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field, wherein the electrical energy is a variable flux.

Nicolau is directed to a method and apparatus for the encapsulation of biologically-active substances in red blood cells.

It is respectfully submitted that Nicolau fails to teach or suggest Applicants' claimed invention. Nicolau does not teach or suggest inventions wherein the electrical energy is a variable flux. Accordingly, it is respectfully submitted that the present invention is patentably distinct from Nicolau .

For at least the reasons given above, Applicants respectfully submit that Claim 22 is allowable over the art of record. Furthermore, since Claims 23-26 and 28-29 recite additional claim features and depend from Claim 22, these claims are also allowable over the art of record. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 25-26 and 28-29 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,090,617 to Meserol *et al.* (hereafter "Meserol '617"). This rejection is respectfully traversed.

Applicants' claimed invention may be relied upon as above.

Meserol '617 is directed to a flow electroporation chamber for electrical stimulation of particles in a saline solution, comprising: a housing having an inlet, an outlet, and internal walls defining a particle electrical stimulation chamber; said chamber being configured to receive a continuous flow of particles from the inlet; and a pair of electrodes disposed along opposing walls of said chamber, said electrodes comprising means for placing said electrodes in electrical communication with a source of electrical energy, whereby flowing particles in said chamber are subjected to an electrical field therebetween; said electrodes each further comprising an external surface wherein at least a portion of the external surface of one of said electrodes corresponding to the emission of the electrical field has a continuous crystalline metal nitride coating. Meserol '617 further includes an invention, wherein the source of electrical energy is adapted to supply pulsed electrical energy; wherein at least a portion the surface of both electrodes corresponding to the electrical field has a continuous crystalline metal nitride coating; wherein the continuous crystalline metal nitride coating is selected from the group consisting of titanium nitride, titanium aluminum nitride, chromium nitride, and zirconium nitride; and wherein the continuous crystalline metal coating is titanium nitride.

It is respectfully submitted that Meserol '617 fails to teach or suggest Applicants' claimed invention. The present invention is not limited to a pair of electrodes. Additionally, Meserol '617 does not teach or suggest inventions wherein the electrical energy is a variable flux. Accordingly, it is respectfully submitted that the present invention is patentably distinct from Meserol '617.

For at least the reasons given above, Applicants respectfully submit that Claim 22 is allowable over the art of record. Furthermore, since Claims 23-26 and 28-29 recite additional claim features and depend from Claim 22, these claims are also allowable over the art of record. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 14-15, 17-26 and 28-29 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 5,720,921 to Meserol *et al.* (hereafter "Meserol '921"). This rejection is respectfully traversed.

Claim 14 is directed to, *inter alia*, an electroporation chamber for poration of biological particles, comprising walls defining a fluid flow path; electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical

energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field; and the apparatus being characterized by at least one of the walls defining the fluid flow path being elastically deformable and at least another one of the walls defining the fluid flow path being substantially rigid, wherein the electrical energy is a variable flux.

Meresol '921 is directed to an apparatus for poration of biological particles, comprising walls defining a fluid flow path; electrodes disposed along opposing sides of said fluid flow path, said electrodes including means for placing said electrodes in electrical communication with a source of pulsed electrical energy, whereby biological particles moving along said fluid flow path are subjected to a pulsed electrical field; said apparatus being characterized by at least one of said walls defining said fluid flow path being elastically deformable and at least another one of said walls defining said fluid flow path being substantially rigid; whereby transient pressure increases within said fluid flow path are at least partially absorbed by said elastic material of said wall.

It is respectfully submitted that Meresol '921 fails to teach or suggest Applicants' claimed invention. Meresol '921 does not teach or suggest inventions wherein the electrical energy is a variable flux. Accordingly, it is respectfully submitted that the present invention is patentably distinct from Meresol '921.

For at least the reasons given above, Applicants respectfully submit that Claim 22 is allowable over the art of record. Furthermore, since Claims 23-26 and 28-29 recite additional claim features and depend from Claim 22, these claims are also allowable over the art of record. Accordingly, Applicants respectfully request withdrawal of this rejection.

### **III. Double Patenting:**

Claims 14-15, 17-26 and 28-29 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U.S. Patent Number 5,720,921 to Meresol. Also, Claims 22-26 and 28-29 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of U.S. Patent Number 5,720,921 to Meresol. Applicants submit that the present invention differs from the patented claims in the above-referenced U.S. patent since Meresol does not teach or suggest inventions wherein the electrical energy is a variable flux. Accordingly, it is respectfully submitted that the present invention is patentably distinct from Meresol '921 and Applicants respectfully request withdrawal of this rejection.

**IV. Conclusion:**

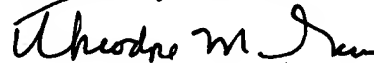
For at least the reasons given above, Applicants respectfully submit that Claims 14-15, 17-26 and 28-29 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

The foregoing is submitted as a full and complete Response to the First Office Action mailed August 15, 2002, and early and favorable consideration of the claims is requested.

Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact Applicants' representative at the telephone number listed below.

A check in the amount of \$55 is enclosed for a one-month extension of time. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**Amendments in the Claims**

In accordance with 37 C.F.R. 1.121(c), the following versions of the specification and claims as rewritten by the foregoing amendments show all changes made relative to the previous version of the specification and claims.

**In The Claims:**

Please amend the claims as follows:

14. (Amended) An electroporation chamber for poration of biological particles, comprising:

walls defining a fluid flow path;

electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field; and

the apparatus being characterized by at least one of the walls defining the fluid flow path being elastically deformable and at least another one of the walls defining the fluid flow path being substantially rigid;

wherein the electrical energy is a variable flux.

20. (Amended) An electroporation chamber for poration of biological particles, the electroporation chamber being removably mounted to a support member, the electroporation chamber comprising:

walls defining a fluid flow path;

electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field and

a mechanism for breaking the electrodes prior to the apparatus being removed from the support member whereby the apparatus cannot be re-used;

wherein the mechanism includes means that are connected to the electrodes employed in the electroporation chamber when the chamber is mounted to a support member for destroying the electrodes prior to the chamber being removed from the support member;  
wherein the electrical energy is a variable flux.

22. (Amended) An electroporation chamber for poration of biological particles, comprising:

walls defining a fluid flow path;

electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field;

a pump for moving the biological particles along the fluid flow path; and

a controller responsive to the rate at which the pump moves the biological particles along the fluid flow path and to the interval between pulses of electrical energy;

wherein the electrical energy is a variable flux.

25. (Amended) An electroporation chamber for poration of biological particles, comprising:

walls defining a fluid flow path;

electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path are subjected to an electrical field;

wherein the electrical energy is a variable flux.